ASTRAZENECA PLC
Form 6-K
May 06, 2014

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of May 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

US FDA APPROVES EPANOVA FOR THE TREATMENT OF ADULTS WITH SEVERE HYPERTRIGLYCERIDAEMIA

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved EPANOVA (omega-3-carboxylic acids) as an adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridaemia (triglyceride levels greater than or equal to 500 mg/dL).

EPANOVA is the first FDA approved prescription omega-3 in free fatty acid form. The dosage of EPANOVA is 2 grams (2 capsules) or 4 grams (4 capsules), making it the first prescription omega-3 to have a dosing option as few as two capsules once a day, with or without food.

"The FDA's approval of EPANOVA is good news for the significant and growing population with severe hypertriglyceridaemia as it offers physicians and their patients an important new treatment option that has been proven to be effective in clinical trials," said Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca. "This approval is a significant milestone for AstraZeneca, as it strengthens our existing portfolio of cardiovascular medicines. We are committed to further assessing the clinical profile of EPANOVA and to identifying other patient groups it may benefit."

Triglycerides are a type of lipid (fat) found in blood and an essential energy source for the body. Some people have very high triglyceride levels (severe hypertriglyceridaemia), meaning they have too much fat in their blood which can lead to serious health complications. Nearly four million American adults currently have severe hypertriglyceridaemia and this figure continues to rise, as the prevalence of associated conditions, such as obesity and diabetes, continues to grow. EPANOVA is a pure, free fatty acid form that can provide physicians with an option to effectively manage the condition without dramatically increasing a patient's pill burden.

The FDA approval was based on data from a clinical development programme that included positive results from the Phase III EVOLVE (EpanoVa fOr Lowering Very High triglyceridEs) trial, which examined the efficacy of EPANOVA in lowering triglycerides and other key lipid parameters in patients with very high triglycerides. The effect of EPANOVA on the risk of pancreatitis or on cardiovascular mortality and morbidity has not been determined.

As part of AstraZeneca's commitment to addressing unmet need in cardiovascular disease, the company is continuing to evaluate the clinical profile of EPANOVA. Through a large-scale cardiovascular outcomes trial, STRENGTH (STatin Residual risk reduction with EpaNova in hiGh cardiovascular risk paTients with Hypertriglyceridaemia), AstraZeneca plans to evaluate the safety and efficacy of EPANOVA on cardiovascular outcomes in combination with statin therapy, in patients with mixed dyslipidaemia who are at increased risk of cardiovascular disease. AstraZeneca also plans to pursue the development of a fixed dose combination of EPANOVA with a statin and plans to file for regulatory approval in other markets for the severe hypertriglyceridaemia indication.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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6 May 2014

-ENDS-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 06 May 2014

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary